

## **REMARKS**

Claims 1-10 have been cancelled without prejudice.

New claims 11-22 have been added which replace original claims 1-10, canceled herein without prejudice.

The new claims are fully supported by the specification as originally filed and are submitted to replace canceled claim 2 and its dependent claims from the original application. In addition, the use of the laminarin is repeatedly disclosed in conjunction with the promotion of regeneration of the cells, e.g., at pages 3-4 and 13-14. Thus, no new matter is added by the amendments herein.

### **Rejection under 35 USC §112**

Claims 1-10 are rejected under 35 U.S.C. 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

New claims 11-22 were drafted in order to overcome the objection raised under 35 U.S.C. 112, and the claims have been placed in Jepson form to make the patentable subject matter more clear. Accordingly, all of the Examiner's objections to the language under 35 § U.S.C. 112 are respectfully traversed.

### **Rejection under 35 USC §102**

Claims 1, 3, 5, 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Di Luzio et al. (Progress in Cancer Research and Therapy (1978), 7 (Immune Modulation Control Neoplasia Adjuvant Ther.), 171-82.

That rejection is respectfully traversed in that original Claims 1, 3, 5, 7 and 9 refer to  $\beta$ -1,3 glucan, while new claims 11-22, which are directed to the subject matter of original claims 2, 4, 6, 8 and 10, refer to laminarin. Since the Examiner did not previously raise any objections under 35 U.S.C. §102 with regard to the original claims referring to the administration of laminarin, the Examiner's outstanding rejection does not apply to new claims 11-22 and has become moot

### **Rejection under 35 USC §103**

Claims 2, 4, 6, 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Di Luzio et al. in view of Yvin et al. (US 2003/0119780 A1).

That rejection, insofar as applied to new claims 11-22, is respectfully traversed.

According to the Examiner, "The difference between applicants' claimed method and Di Luzio et al.'s method is that Di Luzio et al. do not use laminarin".

Applicants respectfully disagree with that analysis at least when taking into consideration the instant invention as defined in the newly presented claims.

In the present new claims, the instant invention is directed to the improvement wherein laminarin is used in conjunction with an antineoplastic agent, especially cyclophosphamide, and promotes the regeneration of the cells in the bone marrow and in the peripheral blood of the patient being treated and, in particular with regard to the granulocytes, these cells undergo an acute reduction under the action of the antineoplastic agent, in particular cyclophosphamide.

Accordingly, the use of laminarin in this manner is novel and unobvious over Di Luzio who discloses enhancement of the inhibitory effect on experimental acute myelogenous leukemia by glucan immunopotential. Laminarin is not identified in Di Luzio.

Moreover, in no case would Di Luzio have had the possibility to identify laminarin among the glucans he is talking about, namely because the glucans selected by Di Luzio were isolated from "saccharomyces cerevisiae" i.e. from yeast, while laminarin is a  $\beta$ -1,3 glucan isolated from brown algae; these two types of glucans are quite different from the point of view of their structure. In particular, yeast glucans are only present in the structure of the cell-walls, while laminarins are consisting of carbohydrate energetic storages present in the cytoplasm of the cell. Structurally, laminarin contains mannitol units which are present as terminal units in more than 2/3 of the laminarin molecules, and that shows that laminarin is a particular structure of  $\beta$ -glucan.

Thus, the skilled artisan could in no way deduce from the Di Luzio's teaching that laminarin could promote the regeneration of the cells and, in particular, of the granulocytes in the bone marrow and the peripheral blood after reduction of their number under the action of an antineoplastic agent.

Nor would Yvin et al. suggest the regenerating activity of laminarin, the Yvin et al. reference merely disclosing the effects of soluble laminarin on tumor growth. Additionally, it is noteworthy that the cited Yvin et al. reference shows the superiority of laminarin in the particular field of tumor growth 'only with respect to the yeast derived glucan BEI used for comparison, as appears from paragraph [0034].

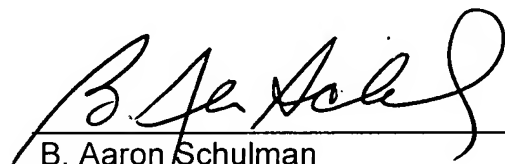
Consequently, the instant invention as defined in the new claims is not only novel but also unobvious over the cited prior art. Thus, the Examiner's rejection under 35 U.S.C. §103 on the basis of the cited references is respectfully traversed and should be withdrawn.

In view of the above amendments and remarks, Applicants respectfully submit that the claims are in condition for allowance. A Notice of Allowance is therefore respectfully solicited. Should the Examiner believe that a discussion with the undersigned counsel would expedite prosecution of the application, a telephone call to (703) 739-4900 would be welcomed.

Respectfully submitted,

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